June 19, 2006

Dissenting Views on H.R. 4157
"Health Information Technology Promotion Act of 2006"

The promise of expanding the use of interoperable health information technology (IT) systems has been widely documented. Information technology applications in the field of health care are expected to yield greater efficiencies and save lives. Total system-wide savings from widespread adoption of health information technology are estimated to range from $81 billion to $160 billion per year when fully implemented.

Unfortunately, HR 4157, as reported by the Committee on Ways and Means, will not advance the goal of a nationwide interoperable health information technology system. In fact, this legislation actually causes greater harm by squandering an important opportunity to establish a clear pathway to achieve interoperability standards and assure widespread adoption. Moreover, the bill will foster fraud, waste, and abuse in the Medicare program, and sets in motion a process to preempt state laws and regulations that protect the privacy and confidentiality of individually identifiable health information.

A number of organizations representing consumers, providers and others wrote to express concerns with the Chairman's Mark and support for several of the Democratic amendments discussed below. Those letters have been inserted in the Record.

PRIVACY PROTECTIONS ARE ERODED

HR 4157, as reported, undermines patients' right to privacy with respect to individually identifiable health information. While the legislation reported out of the Subcommittee on Health contained troubling provisions on privacy, the Chairman's Mark amended the reported bill with a provision that would ultimately clearly preempt state privacy laws that are stronger than the federal law. This is unacceptable.

The federal privacy regulations that resulted from the Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a minimum level of protection at the federal level, while allowing continued application of more protective state laws. As required under the law, the Clinton Administration issued final regulations in 2000, after Congress was unable to agree on privacy legislation in the three years following the passage of HIPAA. The Bush Administration then suspended the rules after taking office in 2001, and proposed modifications and finalized new rules in 2002.

HIPAA applies directly to only providers, insurers, and "health care clearinghouses," though others who use information from these "covered entities" are vicariously subject to HIPAA as "business associates" of the covered entities. Regulatory changes made by the Bush Administration in 2002 authorize the use and disclosure without consent of virtually <u>all</u>

identifiable health information in routine situations – e.g., for treatment, payment, or health care operations (e.g., quality improvement activities; underwriting; business planning and administration, certain fundraising for the benefit of the covered entity, etc.).

Even with these weakened standards, enforcement is passive and virtually non-existent, relying almost exclusively on complaints to trigger investigations. According to the Administration, the Department of Health and Human Services (HHS) has been enforcing the privacy rule since April, 2003, which is the date by which most entities were required to be in compliance, but no penalties have been levied. Plus, even if enforcement were more aggressive, the penalties apply only in narrow, egregious situations and only to covered entities, not to business associates or to individual employees who have actually engaged in the misconduct.

HHS may impose civil money penalties on a covered entity of $100 per failure to comply, not to exceed $25,000 per year. However, HHS may not impose a fine if the violation did not involve willful neglect and the covered entity corrected the violation within 30 days of when it knew or should have known of the violation. In addition, criminal penalties are theoretically available. A covered entity who knowingly obtains or discloses protected health information could be fined $50,000 and face up to one-year in prison; higher penalties and longer terms are available if the case involves false pretenses or the intent to sell, transfer, or use the information for commercial advantage, personal gain, or malicious harm. Regardless, it is important to note that available remedies under federal law, if applied, are provided to the government, not the individual whose information was disclosed or misused.

Efforts to move toward an electronic environment need to enhance – not erode – confidentiality of individually identifiable health information and improve enforcement. Electronic systems make it easier, not harder, to accommodate different laws. Vendors or other software developers can build the various laws into the system, and update as needed. More uniformity may be desirable, but would only be acceptable if it leads to an improvement for all, not an erosion for many.

HIPAA was consciously designed as a floor upon which states could build. As such, its provisions are inadequate in many ways. States have a variety of laws that provide additional protections for certain sensitive information. Some states even provide for a right of action that allows individuals to pursue remedies when information is improperly used or disclosed. Careful consideration and public debate should occur before a weak federal standard is used to preempt stronger state laws. That has not occurred in this Committee.

LACKS A TIMELINE FOR STANDARDS DEVELOPMENT AND ADOPTION

To assure progress on the development of interoperability standards for health information technology, Congress needs to provide leadership and schedule a timeline for action. For more than a decade, adoption of standards has been stalled to protect proprietary interests. In such circumstances, it is necessary for the government to step in to assert the public's interest. Without uniform standards, systems are unable to communicate with one another and the potential benefits of expanding the use of technology in clinical practice remain out of reach.

Although many standards have already been developed, few have been adopted because there is no incentive for providers or venders to adhere to particular standards. As a result, patients and taxpayers have been forced to wait to enjoy the benefits of an interoperable health information technology system. As it stands, HR 4157 does not establish a deadline or even a timeframe for adoption of standards. Accordingly, the legislation fails to lay the fundamental groundwork needed to move forward. The first step toward the vision of an interoperable system is to set a deadline by which standards have to be designated.

LACK OF FUNDING

To spur adoption among providers, Congress should fund acquisition, support, and maintenance of information technology systems that meet the designated standards. At the same time, Congress should ensure that Medicare patients receive the full benefit of health information technology systems by requiring Medicare providers to use such systems. In addition, relevant technology purchased by the federal government and its contractors should also comply with the standards. The system-wide savings expected from the more efficient health system will more than offset the initial investments.

Unfortunately, HR 4157 fails to take these needed steps. There is nothing in the legislation that assures meaningful use of interoperable health technology. Absent widespread or near universal adoption, the potential savings and clinical benefits will never be fully realized. Even more alarming, because the legislation lacks funding and encourages providers to invest in technology that does not meet standards, HR 4157 could actually undermine the goal of widespread adoption by creating perverse incentives for investment in non-interoperable products just prior to the designation of needed standards. This could lead to further entrenchment and commitment to systems that may soon be rendered obsolete.

INCREASES WASTE, FRAUD AND ABUSE

Rather than provide funding for acquisition and support of health information technology, the Chairman's bill presumes that providers themselves will supply equipment and services to other providers. In order to accommodate these relationships, section 3 of the bill creates several exceptions to Medicare's anti-fraud and abuse statutes. These provisions will increase Medicare's vulnerability to waste, fraud, and abuse, and will not result in the level of investment needed to materially advance the adoption of health information technology among hospitals and physician offices.

Most hospitals do not have the capital resources necessary to purchase health information technology for physicians, and many physicians do not want to be beholden to hospitals or other entities for the provision of IT. Poor and rural communities will likely be left behind with this strategy, exacerbating health disparities in under-served populations.

In testimony before the Subcommittee, a large health system that has been a prime advocate for the exception to limitations in the self-referral law admitted that the exception would only benefit a handful of providers that met very specific conditions. Other providers have privately admitted that they want to use information technology to tighten relationships with certain doctors or gain a competitive edge over other hospitals in the market.

At the same time, physicians with privileges at multiple hospitals do not want to be locked into one hospital in their community, particularly when a hospital that has extra resources to purchase information technology is likely to already be more dominant. Conversely, forcing doctors to maneuver between multiple information technology systems to accommodate various hospitals in their community is inefficient, undesirable and not feasible. Furthermore, hospital-level systems may be inappropriate for physician practices, and physicians are rightfully concerned about hospitals "owning" their patients' data.

Creating safe harbors that encourage purchase of information technology prior to the adoption and certification of standards, as this legislation would do, will exacerbate current problems relating to multiple systems that are not interoperable. It will also undermine interest in moving forward with compliant systems when standards are in place. Promoting immediate investment in and subsequent adoption of systems that are not interoperable or do not meet standards will only impede future progress by encouraging stove-piping, waste, and "buy-in" to old systems.

The Centers for Medicare and Medicaid Services (CMS) and the HHS Office of the Inspector General (OIG) are predicted to issue a final rule by the end of this year that would create tightly-crafted safe harbors enabling these transactions. It is difficult to draft safe harbors that balance the need to maintain program integrity while permitting previously impermissible activities; involvement of CMS, OIG and the Department of Justice is critical, yet this does not appear to have happened in the drafting of HR 4157.

Finally, the Congressional Budget Office has sent a letter, as seen in the Record, indicating that section 3 will increase Medicare spending because of the induced services and other increased waste, fraud, and abuse expected as a result of these provisions. A precise estimate is not available at this time.

DEMOCRATIC AMENDMENTS

Mr. Emanuel and Mr. Doggett offered an amendment, which was defeated on a party-line vote, to strengthen current HIPAA protections. This amendment would have replaced section 4 with provisions to improve and preserve privacy, confidentiality and security protections for individually identifiable health information in the new electronic environment. The amendment included provisions that would have –

(1) created a consent requirement;
(2) required breach notification to affected individual(s) and the Secretary;
(3) extended the application of rules and protections to all entities;
(4) established safeguard requirements; and

(5) provided access to damages and other relief for individuals whose information is inappropriately disclosed or used.

In addition, Mr. Stark offered an amendment to protect from pre-emption state laws that provide greater protection of information relating to mental health, substance abuse, rape, incest and other domestic violence, family planning, HIV, sexually transmitted diseases, screening for and presence of genes or genetic markers, and other sensitive areas as designated by the Secretary, or permit individuals to pursue legal action against an entity that improperly uses or discloses identifiable health information. This amendment was also defeated on a party-line vote.

Two additional amendments would have addressed timeline and funding concerns. The first, offered by Mr. Emanuel, would have established a process for the Secretary to develop and approve interoperability standards within 24 months of enactment if the process set forth in section 2 of the bill did not produce standards within 18 months of enactment. The amendment also directed the Secretary of HHS to establish a Medicare payment to finance the purchase of health information technology that meets specified standards. Finally, the amendment would have required Medicare providers – including Medicare Advantage and Part D plans – to use electronic health records with the core functionalities identified by the Institute of Medicine in their correspondence to HHS, "Key Capabilities of an electronic Health Record System" (July 31, 2003).

An amendment offered by Mr. Thompson proposed to give Medicare providers the financial assistance necessary to purchase, support, and maintain health information technology systems. Recognizing that the cost of such systems is still unknown, the amendment gave broad authority for the Secretary of HHS to determine the appropriate amount and manner of distributing these funds. Funding would be available to all providers, including integrated delivery systems whose systems needed to be conformed to meet the new standards. However, given the current payment structure for Medicare Advantage plans, most plans would have been ineligible for additional funding under this provision.

Although it is widely acknowledged that direct financing is an essential component for widespread adoption of health information technology, these two amendments were defeated on party-line votes.

Finally, Mr. Stark offered an amendment to strike section 3. It was also defeated on a party-line vote.

CONCLUSION

Democrats want to see widespread adoption of inter-operable health information technology systems be a reality. That's why amendments were offered to ensure progress on this critical front.

Lack of ready access to critical information in a patient's medical record has resulted in massive inefficiencies, sub-optimal quality of care, and even death. The longer the Congress waits to

provide the leadership necessary to progress toward a fully interoperable health information technology system, the more damage that is done. Unfortunately, HR 4157 as reported by the Committee misses the mark. Even worse, if passed in its current form, this bill may hinder the development of interoperable medical records for years to come.

The promotion of health information technology should not be a partisan undertaking. However, the Committee leadership has made it so every step of the way: rejecting our suggestions and potential compromise positions to early drafts of the bill, not seeking input from the minority in constructing a manager's amendment, and defeating each of our amendments on party-line votes.

In contrast, the Senate unanimously passed a bill (S 1418) to establish standards and certification processes for interoperability within a year of enactment, and to provide funding to help health care providers acquire and support the expanded use of information technology in their practices. Although S 1418 does not go as far as we would like, it is significantly better than the bill the Committee recommended.

We look forward to correcting the deficiencies in HR 4157 prior to final passage by the House in order to send into conference with the Senate a strong bill with timelines for action, clear guidance for advancement, financial support, and improved patient privacy protections.

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